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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,271	02/18/2004	Borzu Sohrab	LIFE-017CON2	4224

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EXAMINER

BERHANU, ETSUB D

ART UNIT	PAPER NUMBER
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3768

DATE MAILED: 07/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/782,271

Applicant(s)

SOHRAB, BORZU

Examiner

Etsub D. Berhanu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 10-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2/18/04 3/14/05
4/26/2005 6/29/2005
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Claim Objections

1. Claim 14 is objected to because of the following informalities: "preformed" in line 1 should be amended to read -- performed --. Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 10-16 and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Kollias et al.'059 (US Patent No. 6,505,059).

Kollias et al.'059 discloses a method of managing the blood glucose concentration of a host, the method comprising: automatically measuring the glucose concentration of a host a plurality of times over a predetermined time period and according to a predetermined schedule, comparing the plurality of glucose concentration measurements to a reference pattern of glucose concentrations and administering insulin to the host in response to the comparison of measurements, wherein each step of the method is performed by the device (col. 12, lines 16-56 and col. 8, line 63 – col. 9, line 2), and wherein the measurements are made in situ (col. 2, lines 4-5). Kollias et al.'059 further discloses that the steps of the method are performed by a device worn on the host, wherein the device comprises a plurality of single-use glucose measurement means provided within a removable housing (col. 11, lines 2-5 and col. 12, lines

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9-11), and that the steps of measuring the glucose concentration and comparing the measurements to a reference pattern of glucose concentrations are continuous, thus repeated (col. 9, lines 7-11).

4. Claims 10-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Say et al.'752 (US Patent No. 6,175,752).

Say et al.'752 discloses a method of managing the blood glucose concentration of a host, the method comprising: automatically measuring the glucose concentration of a host a plurality of times over a predetermined time period (col. 5, lines 34-37) and according to a predetermined schedule (col. 44, line 67 – col. 45, line 4), comparing the plurality of glucose concentration measurements to a reference pattern of glucose concentrations and administering insulin to the host in response to the comparison of measurements (col. 54, line 66 – col. 55, line 5). Say et al.'752 further discloses that the steps of the method are performed by a device worn on the host, wherein the device comprises a plurality of single-use glucose measurement means provided within a removable housing, and that the steps of measuring the glucose concentration and comparing the measurements to a reference pattern of glucose concentrations are continuous, thus repeated, and performed in vivo (col. 2, lines 13-31). Say et al.'752 further discloses modifying the scheduling mode, wherein modifying the scheduling mode comprises increasing the frequency of automatically measuring the glucose concentration (col. 43, lines 13-20).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 10 and 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Aceti et al.'675 (cited by applicant) further in view of Say et al.'752.

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Aceti et al.'675 discloses a method of managing the blood glucose concentration of a host, the method comprising: automatically measuring the glucose concentration of a host a plurality of times over a predetermined time period and according to a predetermined schedule (col. 6, lines 38-40 and col. 11, lines 37-42), and administering insulin to the host in response to the comparison of measurements (col. 11, lines 26-32), wherein the measurements are made ex vivo (Figure 5 and col. 4, lines 31-46).

Aceti et al.'675 does not disclose a method step of comparing the plurality of glucose concentration measurements to a reference pattern of glucose concentrations.

Say et al.'752 teaches comparing a plurality of glucose concentration measurements to a reference pattern of glucose concentrations to predict hypoglycemia or hyperglycemia and deliver insulin accordingly (col. 54, line 66 – col. 55, line 5).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Aceti et al.'675 to include comparing a plurality of glucose concentration measurements to a reference pattern of glucose concentrations, as taught by Say et al.'752, since it would allow the prediction of hypoglycemic or hyperglycemic events and would allow the device of Aceti et al.'675 to deliver insulin accordingly. It is noted that Aceti et al.'675 discloses that insulin is a drug used to maintain glucose levels (col. 1, lines 19-25).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Etsub D. Berhanu whose telephone number is 571.272.6563. The examiner can normally be reached on Monday - Friday (Every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on (571)272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

EDB

ERIC F. WINAKUR
PRIMARY EXAMINER
